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(54) **Test elements and method for manufacturing thereof.**

(57) Test elements for use in clinical analyzers are usually assembled from a number of components which have fairly complex shapes and then bonded together using ultrasonic welding techniques. This r quires careful assembly to provide adequate bonding. Described herein is a novel slide test element (10) and a method of its manufacture. The test el m nt (10) comprises a frame member (20) having a recess (32) in which is retained a reaction member (12). An overhanging lip (34) is formed in a sidewall of th recess (32) to hold the reaction member (12) in position once assembled. Assembly is achieved by b nding the frame member (20) with the lip (34) facing outwardly, forcing it to part a distance sufficient to allow the reaction member (12) to be inserted, and then relaxing the frame member (20) once the reaction member (12) has been ins rted.

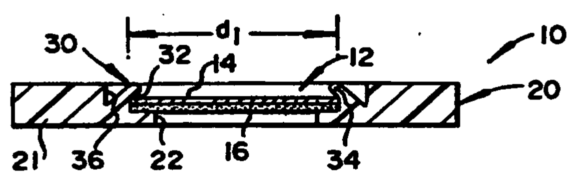

FIG. 1

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This invention relates to slide-like test elements for us in clinical chemistry and a method for their manufacture.

The clinical analysis of biological fluids is most conveniently done using so-called "dried" slide-like test l ments which have no wet reagents in liquid form. Prior to this invention, such elements have be n manufactured from three or four separate pieces that have to be assembled and sealed together. US-A-4 169 751 is illustrative of a useful proc ss, wherein four lock tabs are formed in the sidewalls of a recess in one of the pieces of the fram member or holder, and then bent over to lock a reaction member bearing reagents, which is inserted into the recess.

Although those test elements and assembly m thods have been very useful, the method does involve a number of components specifically manufactur d with fairly complex shapes, and assembly using ultrasound. Such a process has to be used carefully to assure adequate bonding. Furthermore, more parts for assembly requires more quality control of the finished product. There has been a need, therefore, to reduce the number of component parts and to simplify the manufacturing procedure.

Still further, the aforesaid process requires either that both the frame member and reaction memb r be made at the same site prior to assembly, or that if made at separate sites, the preformed frame members be shipped to the assembly site. The latter step involves collection of frame m mbers and packaging, which if not done correctly can make reorientation of the frame members difficult during subsequent assembly. In particular, a loose, random collection of frame members in a package would necessitate proper reorientation at the assembly site before they can be used.

Therefore, it has been a problem to improve the packaging of such pre-formed frame members if such have to be shipped.

It is therefore an object of the present invention to provide a manufacturing process which solves the above-noted problems, and also which produces an assembled slide-like test element having novel f atures.

More specifically, in accordance with one aspect of the present invention, there is provided a test element for analytical assays of biological liquids comprising:-

a r action member including one or more layers on a support, each layer including a reagent, and

a frame m mber for th r action member comprising a base portion having an apertur generally center d on but small r in diam ter than the dimensions of the r action m mber,

characterized in that th t st element further includes a recess formed in th base portion of the frame memb r of dimensions large enough to hold the reaction member so as to overlay the aperture formed in the base portion, a lip overhanging the recess and the reaction member in the recess, the lip extending for a majority of the distance around the recess to confine the reaction member in place in the recess, and an exposed groove immediately adjacent to at least a portion of the lip.

In accordance with a second aspect of the present invention, there is provided a method of assemblying a slide-like test element comprising a reaction member and a frame member, the method comprising the steps of:-

a) forming a cold-flowable frame member with an opening therein dimensioned to fit the dimensions of the reaction member; and

b) forming a reaction member with outside dimensions selected to allow it to fit within the opening;

characterized in that the step a) comprises the steps of:-

i), for each frame member, first forming an aperture passing through the frame member which is smaller in dimensions than the opening to be formed,

ii) thereafter forming the opening as a recess in the frame member which is generally centered on and overlies the aperture with sidewalls;

iii) cold-flowing at least a portion of the sidewalls to form a lip which overhangs the opening and is shaped to hold the reaction member in place.

In accordance with a third aspect of the present invention, there is provided a method of assemblying a slide-like test element which requires the insertion of a reaction member into a pre-formed frame member, the method comprising the steps of:-

a) forming a heat-fusible plastic frame member with an opening therein;

b) forming a reaction member with outside dimensions selected to allow it to fit within the opening; and

c) assemblying the reaction member with the frame member;

characterized in that step a) is followed by the further step of forming a stack of frame members and temporarily fusing them to one another by heating at least a portion of at least one side edge of each fram member to form an adhesion stripe.

Accordingly, it is an advantageous feature of the inv ntion that a method of making a t st element is provided that has fewer steps and fewer separate parts to k ep track of.

It is a related advantageous feature that the process liminates the n d for ultrasonic bonding.

It is a further related advantageous features that a novel test element results from this method.

Another advantageous feature of the invention is that pre-formed frame members to be used to assemble the test element can be readily packaged and shipped without complicating subsequent assembly.

For a better understanding of the present inv ntion, reference will now be made, by way of xample only, to the accompanying drawings in which:-

Figure 1 is a sectioned elevational view of a test l ment prepared in accordance with the present invention;

Figure 2 is a top plan view of the test element shown in Figure 1;

Figures 3A to 3E are sectional elevational views, some fragmentary, illustrating a preferred method of preparing a frame member for the test element according to the present invention;

Figure 4 is an elevational view similar to that shown in Figure 3D, but illustrating a staking tool;

Figure 5 is a fragmentary isometric view of a package of frame members prepared according to Figures 3A to 3E, after shipment to an ass mbly site, illustrating the de-packaging step;

Figure 6 is a fragmentary isometric view illustrating a method of adhesion of the stack members prior to shipment;

Figures 7A to 7D are sectioned elevational views illustrating the process steps of assembly using the frame members prepared in the steps shown in Figures 3A to 3E;

Figures 8A and 8B are sectioned fragmentary levational views illustrating an optional locking step which further secures the assembly;

Figure 9 is a top plan view of an assembled test lement finished as shown in Figures 8A to 8B; and

Figures 10A and 10B are elevational views similar to those shown in Figures 3A to 3E, illustrating another manufacturing process of the invention.

The invention is described hereinafter in connection with its preferred embodiments, wherein a colorimetric test element of a preferred construction is prepared by assemblying a reaction member with reag nts, into a flexible frame m mber of preferably heat-fusible plastic. The ass mbly steps f ature cold-flow formation of th plastic, packaging of the formed plastic by a temporary h at-fusion step, and/or b nding of th unpackaged, plastic fram member to insert the reaction member made at a diff rent location.

In addition to such pref rr d emb diments, the invention is applicabl to any t st lement for analytical assays, regardless of the type of reaction performed by the reaction member, so long as it involves an overlying lip in a frame member having the features set forth hereinafter. Also, the steps of cold-flow member formation and assembly by bending are further applicable whether or not the frame member is of a heat-fusible plastic, and whether or not the pre-formed frame member is shipped without the reaction member by assemblying a stack of such frame members and temporarily adhering them together. Still further, the assembly methods of the invention are equally applicable when the reaction member is made at the assembly site in previous steps, rather than at a site different from the assembly site.

As shown in Figures 1 and 2, a slide test element 10 constructed in accordance with this invention comprises a reaction member 12 and a frame member 20. The reaction member is conventional and comprises a transparent support 14 and thereon at least one layer 16 containing at least one reagent needed to produce a detectable change in response to a targeted analyte in a patient liquid, the change being quantitative in accord with the amount of analyte present. Most preferably, member 12 provides a colorimetric assay, and such are well-known both in the patent literature and the commercial world, for example those elements available under the trademark "Ektachem" slides from Eastman Kodak Company. Other conventional elements also feature such a frame member holding a reaction member, for example ion-selective electrode (ISE) elements, which if using an electrode of curved shape, can also be made according to this invention. ISE elements have as their reagent(s), at least an ionophore which selectively associates with and carries the ion of choice across an ion-selective membrane.

Regarding frame member 20, these conventionally comprise a flexible, heat-fusible plastic base 21 of a generally planar shape, having a fluid-metering aperture 22 extending all the way through and means 30 for holding the reaction member in place over aperture 22. Of necessity, aperture 22 is smaller in dimensions than the reaction member that overlies it.

In accordance with one aspect of the invention, holding means 30 preferably comprise a recess 32 in bas 21, of dimensions such as diamet r d_1 which are large enough to retain r action memb r 12, and a lip 34 overhanging that recess and th r action memb r, thus holding in place the r action member. As shown in Figur 2, lip 34 pref rably extends at least the majority of the distance around the circumference of recess 22. As used herein, "majority" means at least 51%. Most preferably, it

extends the entire distanc around rec ss 32. Still further, the holding m ans compris a groov 36 which is substantially co-extensive with lip 34 simply because it is co-formed with lip 34. Most preferably, the shapes in plan view of lip 34 and groov 36 are those of an annulus. Lip 34 thus d fines the viewing aperture of element 10.

Because of the presence of lip 34, no other retaining means is needed to hold reaction member 12 within recess 32.

Such a slide element is made by a process of 1) forming separately the frame member and the reaction member, 2) optionally stacking together individual frame members for shipment to an assembly site, and then 3) assemblying the reaction member into the frame member. Each of these three steps has been improved upon in aspects of the invention, as follows:

Th methods of forming the reaction members are known and conventional, and do not comprise any part of this invention. It is the frame member m thod of formation that is novel, as follows:

In the sequence shown in Figures 3A to 3E, a single frame member 20 is depicted for clarity as it moves through its various stages shown as 20A, 20B, etc. However, it will be appreciated that the discussion that follows can be applied to a side-by-sid array of such individual members temporarily link d together as part of a common, preferably continuous web as shown, for example, in US-A-4 668 472. After the formation of frame member 20 is complete, as shown in Figure 3E, those connected memb rs are then simply severed at their temporary link.

Thus, as shown in Figure 3A, plastic base 21 of fram member 20A has a top surface 23 and is apertur d at 22' by a conventional punch, not shown. Thereafter, it is moved to the next station in the process (Figure 3B) where a punch 40 is brought down to cold-form the upper portion 42 of base 21 to form recess 32 having sidewalls 44. This usually results in a reshaping of aperture 22' so as to shrink it to aperture 22 of a smaller diamet r (Figure 3C). As noted above, recess 32 is aligned with and generally centered on, but larger in dim nsions than, aperture 22 of frame member 20B. (The center of recess 32 can be misaligned with th center of aperture 22 as much as 0.05mm, for example.) Next (Figure 3D) a specialized punch 50 is brought down to modify sidewalls of recess 32. Staking tool 50 comprises a mandrel cylinder 52 and a concentric, relatively movable forming sl eve 80. Mandrel cylinder 52 has an axis 54 and includes an end portion 56 having outsid dimensions machined to fit snugly within r cess 32. Spaced up axis 54 from nd 56 a distance d_2 is a groove 70 which extends around th circumf rence of cylinder 52 the same amount as lip 34 is to xt nd around r c ss 32. Distanc d_2 is s l ct d to ensur that groove 70 falls inside of r cess 32, under top surface 23 of base 21 (Figur 3E). When cylinder 52 is in place, it sits loosely within recess 32, ready for movement of sleeve 80. Optionally, cylinder 52 can also include a boss 72 extending downward (Figure 3D) from end portion 56, with reduced outside dimensions selected to loosely fit within aperture 22, as shown in phantom in Figure 3E.

Sleeve 80 is provided with a cutting or staking edge 82 the function of which is to cold-flow or "coin" wall 44 of recess 32 into the lip 34 described above. Groove 70 then functions to assist in the shaping of the lip. The "bite" of edge 82 causes the co-formation of groove 36. Frame member 20C is thus complete, when punch 50 is withdrawn. Most preferably, this is done by removing first sleeve 80, and then cylinder 52, so that end portion 56 can slide past lip 34.

It will be recognized that the frame member so produced (Figure 3E) is assymmetric when considered about mid-plane 84. Top surface 23 is not a mirror image of the under-surface at which aperture 22 is located.

Optionally, as shown in Figure 4, the mandrel cylinder can have its lip-forming groove extending for most of the length of the cylinder axis. Parts similar to those previously described bear the same reference numeral to which the distinguishing suffix "A" is appended. Thus, punch 50A comprises cylinder 52A and relatively and separately movable sleeve 80A having a staking edge 82A. End portion 56A of cylinder 52A is also as described before. However, edge 82A is slightly more blunt than before, and groove 70A becomes the outside diameter of cylinder 52A, except for end portion 56A which is dimensioned as before to snugly fit within recess 32 of the frame member. Still further, edge 82A does not extend straight back to inner diameter 90 of sleeve 80A, but rather is rounded off at 92. This rounding of edge 82A acts in concert with end portion 56A to coin out the lip of the frame member, as will be readily appreciated.

At this point, the frame members so produced are ready for assembly, described in detail hereinafter, with reaction members conventionally produced as noted above. This assembly can be done at the site where the finished frame members have just been produced, as a continuation of the assembly process described abov .

Optionally, however, and in accordance with anoth r aspect of the invention, the produced frame members can be packaged and shipped to an assembly site remote from the site of formation of the frame memb rs. The packaging in such a case needs to be carefully arranged to minimize

improp r ori ntation of the fram memb rs. Ideally the members should all b shipped so that all of the top surfaces 23 are facing the same direction, due to the element assymmetry produced as noted above.

To achieve this end, a stack 100 of the frame members 20 is produced, as shown in Figure 5, in which each member is temporarily fused to adjacent members along at least a portion of one side edge 102 of each, the fusion creating an adhesive stripe 104 that may, or may not, be generally parallel to the axis of symmetry 106 of the stack. Similarly, the stack preferably, but need not, have side edges 102 be directly aligned and coplanar throughout the stack, so that the plane of each frame member may (or may not, respectively) be generally perpendicular to axis 106.

The fusion proceeds as is generally described in US-A-4 662 974 and US-A-4 811 861, except here applied to frame members 20. This is possible because of the preferable use of heat-fusible plastic as the material of frame members. The preferred process, as shown in Figure 6, is one in which the frame members 20 so produced as described above are aligned in a stack 100 which is oriented against a support 108, preferably between pressurized guide rails 110 to hold the stack togeth r as a force 112 is applied. Most preferably, stack 100 is horizontal at this juncture, although it can be inclined. Aperture 22 can be the advancing side, as shown, or top surface 23 can be the advancing surface. While the frame members 20 so advance, an air gun 120 applies a jet 122 of hot gases (for example, air) against side edges 102 to form the fusion stripe 104. The temperature of the gas jet should be 200-215 °C if frame members 20 are polyethylene, and higher for polystyrene. The pressure of the jet is variable, and a useful pressure includes 4.9kPa (50cm of water).

Stripe 104 so formed represents a surface phenomenon only, such that substantially no shape deformation occurs at side edges 102. That is, when a frame member is "shucked" from the stack, in the direction indicated by arrow 126 in Figure 5, it is difficult to detect with the unaided eye where the stripe had been applied - a feature that is important in producing a frame member with gen rally uniform side edges. Still further, the fusion at the surface only, renders the members readily separatable from the stack, as described below.

The stack 100 is thus suitable for shipment as is, or wrapp d in a simple protective bag. Because of th adhesion in the stack, ther is no dang r memb rs 20 will reorient during shipment.

At the assembly site, the first step in th process (Figure 5) is to "shuck" off each frame member 20 as ne d d. Most pr ferably, the undersurface of th frame members with ap rtur 22 expos d, is up. Alternatively, if top surface 23 is up, as shown, when the individual members are removed from the stack, they are flipped over 180°, as shown by arrow 130, for reasons that will become apparent.

The "shucking" is achieved by shearing each member 20 to break the adhesion at stripe 104, using a pusher mechanism of some kind, for example, a pusher blade 136, while holding the stack in place by suitable means (not shown). Stripe 104 is a surface adhesion only, as noted above, such that the shear force that is required is minimal, for example 9.8N to 29.4N (1 to 3 kg of force) applied to a side edge 138 having a surface area of 15mm^2.

The non-severed frame members are ready for assembly, which optionally proceeds in accordance with yet another aspect of the invention (Figures 7A to 7D). Each frame member 20 in its upside-down orientation (Figure 7A) is placed within a die 200 having an upper member 202 and a lower member 204, both of which have a generally mating curved surface 212 and 214, respectively. Member 204 is also apertured at 205, with dimensions, for example, an inside diameter, which are generally between the inside diameter groove 36 and the inside diameter of lip 34. The radii of curvature of surfaces 212 and 214 is selected to bend member 20 as shown in Figure 7B, sufficiently to "open up" lip 34 to about the dimensions of aperture 206 in lower member 204.

Next (Figure 7C), a punch 220 of the same or a smaller diameter than that of reaction member 12 and smaller than the inside diameter of aperture 206, is brought up through aperture 206, carrying a reaction member 12 with it, preferably with a liquid-receptive layer up, in contact with punch 220. Preferably, punch 220 is used to punch out individual reaction members 12 from a web. In this manner, reaction member 12 is inserted past lip 34 and into the opening of recess 32.

Next, relative movement is provided between upper member 202 and lower member 204, to allow frame member 20 to straighten out. For example, upper die member 202 can be raised while punch 220 continues pushing upward, and member 202 is raised at a faster rate than punch 220 to effectively relax and straighten out frame member 20 as it lifts off lower member 204 (Figure 7D). (M mber 202 is not shown.) As a r sult, lip 34 clos s over reaction m mber 12, and assembly is essentially complet for slide t st elem nt 10. Element 10 is then remov d by any convenient apparatus, for packaging.

Lip 34 is eff ctiv at this stage to hold m mber 12 within frame member 20. It is possible, however, for creep to occur during storage, such that lip 34

could pull back into groove 36. To deter this, further processing can b appli d (as shown in Figur s 8A and 8B) to further anchor lip 34 in place over reaction member 12. Parts similar to those pr viously described bear the same reference numeral, to which a distinguishing suffix "X" has be n added.

Thus, as shown in Figure 8A, frame member 20X holds reaction member 12X in recess 32X via lip 34X, as described above, a groove 36X being left behind as a result of the lip formation. To further stake lip 34X against release of member 12X, a knife edge 250 is aligned with inside surface 252 of groove 36X, preferably all around the circumfer nce of lip 34X. After edge 250 is brought into th groove about 1/3 to 1/2 of the thickness of fram member 20X, and then withdrawn, in the direction shown by arrow 254, it leaves behind a ridge 260 running throughout groove 36X wherever th knife edge contacted the groove. Next (Figure 8B), a blunt edge 270 is brought down to cold-flow by squashing ridge 260, leaving a generally flattened surface 272 behind. It is these knifing and squashing steps which further displace material against lip 34X, in the direction shown by arrow 274, thus further ensuring its lock against accidental r moval of member 12X from the test element.

It will be readily apparent that the plan view of slide l ment 10X so prepared (Figure 9) is slightly different from that shown in Figure 2, due to the cr ation of additional vertical edge 290 by the process of Figures 8A and 8B. As in the case of the element of Figure 2, aperture 22X is hidden from view and is shown in phantom only.

There is yet another method of manufacture which will produce a test element generally as described for Figure 1. This alternate method is depicted in Figures 10A and 10B. Parts similar to thos previously described bear the same reference numeral, to which the distinguishing suffix "Y" is appended. Thus, in Figure 10A, a frame member 20Y is formed as described above with apertur 22Y and recess 32Y, and reaction member 12Y is also prepared as previously described. However, unlike the previously described method, r action member 12Y is lowered into recess 32Y, in the direction of arrows 300. Thereafter (Figure 10B), a swaging die 302 is lowered and then raised, in the direction of arrows 304, to cut into top surface 23Y of member 20Y to cold-form lip 34Y, and the corresponding groove 36Y, which extends and ov rhangs a majority of the circumferenc of member 12Y, to hold it in.

The inv ntion disclosed herein may be practic d in the absence of any el ment which is not sp cifically disclos d herein.

Claims

1. A test element (10; 10X; 10Y) for analytical assays of biological liquids comprising:-
   a reaction member (12; 12X; 12Y) including one or more layers (16) on a support (14), each layer (16) including a reagent, and
   a frame member (20, 20A, 20B, 20C; 20X; 20Y) for the reaction member (12; 12X; 12Y) comprising a base portion (21) having an aperture (22; 22Y) generally centered on but smaller in diameter than the dimensions of the reaction member (12; 12X; 12Y),
   characterized in that the test element (10; 10X; 10Y) further includes a recess (32; 32X; 32Y) formed in the base portion (21) of the frame member (20, 20A, 20B, 20C; 20X; 20Y) of dimensions large enough to hold the reaction member (12; 12X; 12Y) so as to overlay the aperture (22; 22Y) formed in the base portion (21), a lip (34; 34X; 34Y) overhanging the recess (32; 32X; 32Y) and the reaction member (12; 12X; 12Y) in the recess (32; 32X; 32Y), the lip (34; 34X; 34Y) extending for a majority of the distance around the recess (32; 32X; 32Y) to confine the reaction member (12; 12X; 12Y) in place in the recess (32; 32X; 32Y), and an exposed groove (36; 36X; 36Y) immediately adjacent to at least a portion of the lip (34; 34X; 34Y).

2. A test element according to claim 1, wherein the lip (34; 34X; 34Y) comprises the sole means for retaining the reaction member (12; 12X; 12Y) in the recess (32; 32X; 32Y).

3. A test element according to claim 1 or 2, wherein the exposed groove (36; 36X; 36Y) extends completely around the lip (34; 34X; 34Y) adjacent thereto.

4. A test element according to any one of claims 1 to 3, wherein the recess (32; 32X; 32Y) is generally circular and the lip (34; 34X; 34Y) and the groove (36; 36X; 36Y) each form an annulus.

5. A method of assemblying a slide-like test element (10; 10X; 10Y) comprising a reaction member (12; 12X; 12Y) and a frame member (20, 20A, 20B, 20C; 20X; 20Y), the method comprising the steps of:-
   a) forming a cold-flowable fram member (20, 20A, 20B, 20C; 20X; 20Y) with an op ning (32; 32X; 32Y) therein dimensioned to fit the dimensions of the reaction member (12; 12X; 12Y); and

b) forming a reaction member (12; 12X; 12Y) with outside dimensions selected to allow it to fit within the opening (32; 32X; 32Y);

characterized in that the step a) comprises the steps of:-

i) for each frame member (20, 20A, 20B, 20C; 20X; 20Y), first forming an aperture (22; 22Y) passing through the frame member (20, 20A, 20B, 20C; 20X; 20Y) which is smaller in dimensions than the opening (32; 32X; 32Y) to be formed,
ii) thereafter forming the opening (32; 32X; 32Y) as a recess in the frame member (20, 20A, 20B, 20C; 20X; 20Y) which is generally centered on and overlies the aperture (22; 22Y) with sidewalls (44);
iii) cold-flowing at least a portion of the sidewalls (44) to form a lip (34; 34X; 34Y) which overhangs the opening (32; 32X; 32Y) and is shaped to hold the reaction member (12; 12X; 12Y) in place.

6. A method according to claim 5, wherein the lip (34; 34X; 34Y) completely surrounds the opening (32; 32X; 32Y).

7. A method according to claim 5 or 6, wherein the opening (32; 32X; 32Y) is filled with a protective mandrel during the cold-flowing step.

8. A method of assemblying a slide-like test element (10; 10X; 10Y) which requires the insertion of a reaction member (12; 12X; 12Y) into a pre-formed frame member (20, 20A, 20B, 20C; 20X; 20Y), the method comprising the steps of:-

a) forming a heat-fusible plastic frame member (20, 20A, 20B, 20C; 20X; 20Y) with an opening (32; 32X; 32Y) therein;
b) forming a reaction member (12; 12X; 12Y) with outside dimensions selected to allow it to fit within the opening (32; 32X; 32Y); and
c) assemblying the reaction member (12; 12X; 12Y) with the frame member (20, 20A, 20B, 20C; 20X; 20Y);

characterized in that step a) is followed by the further step of forming a stack (100) of frame members (20, 20A, 20B, 20C; 20X; 20Y) and t mporarily fusing them to one another by h ating at least a portion of at least on side dge (102) of each fram member (20, 20A, 20B, 20C; 20X; 20Y) to form an adhesion strip (104).

9. A method according to claim 8, wh rein step c) includ s the further step of sh aring off a frame member (20, 20A, 20B, 20C; 20X; 20Y) from one end of the stack (100) by pushing against the end member (20, 20A, 20B, 20C; 20X; 20Y) prior to insertion of the reaction member (12; 12X; 12Y).

10. A method according to claim 8 or 9, wherein the frame member (20, 20A, 20B, 20C; 20X) is formed out of a flexible polymer with a lip (34; 34X) around and projecting out over the opening (32; 32X), and wherein step c) comprises the steps of:-

i) bending the frame member (20, 20A, 20B, 20C; 20X) to force the lip (34; 34X) to pull away from the opening (32; 32X) a distance greater than the dimensions of the reaction member (12; 12X);
ii) inserting the reaction member (12; 12X) past the lip (34; 34X) and into the opening (32; 32X); and
iii) relaxing the frame member (20, 20A, 20B, 20C; 20X) and the lip (34; 34X) so that it returns to dimensions which are effective to hold the reaction member (12; 12X) in the opening (32; 32X).

11. A method according to claim 10, wherein the bending step comprises placing the frame member (20, 20A, 20B, 20C; 20X) on a curved surface (204), the facing direction of the lip (34; 34X) and the curvature of the surface (204) being sufficient to pull the lip (34; 34X) away the distance.

12. A method according to any one of claims 8 to 11, wherein each frame member (20, 20A, 20B, 20C; 20X; 20Y) is formed by the following steps:-

i) first forming an aperture (22; 22Y) passing through the frame member (20, 20A, 20B, 20C; 20X; 20Y), the aperture (22; 22Y) being smaller in dimensions than the opening (32; 32X; 32Y) to be formed;
ii) forming the opening (32; 32X; 32Y) as a recess in the frame member (20, 20A, 20B, 20C; 20X; 20Y) which is generally centered on and overlies the aperture (22; 22Y) with sidewalls (44); and
iii) cold-flowing at least a portion of th sidewalls (44) to form an overhanging lip (34; 34X; 34Y) which ov rhangs the opening (32; 32X; 32Y) and is shaped for holding in place a reaction m mber (12; 12X; 12Y).

13. A method according to claim 8 or 9, wher in the frame members (20, 20A, 20B, 20C; 20X;

20Y) and the r action members (12; 12X; 12Y) are formed at separate sites and the stack (100) of frame members (20, 20A, 20B, 20C; 20X; 20Y) is transported to a location suitable for assembly.

14. A method according to claim 8 or 9, wherein a portion (34Y) of the frame member (20Y) adjacent the opening (32Y) is bent over the reaction member (12Y) to retain it in position within the frame member (20Y), the portion (34Y) being formed by cold-flowing the frame member (20Y) adjacent the opening (32Y) after the reaction member (12Y) has been placed in the opening (32Y) as a lip which extends around the majority of the circumference of the opening (32Y).

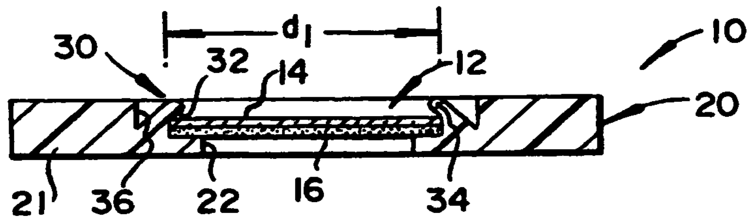


FIG. 1

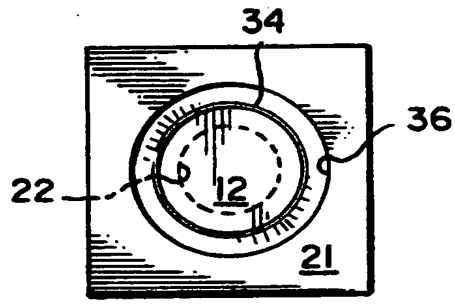


FIG. 2

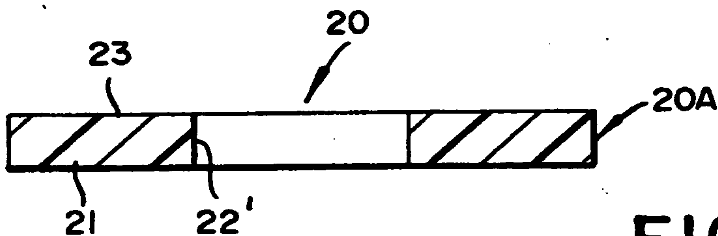


FIG. 3A

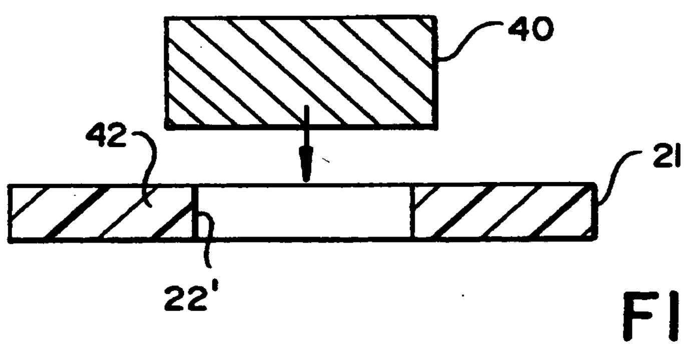


FIG. 3B

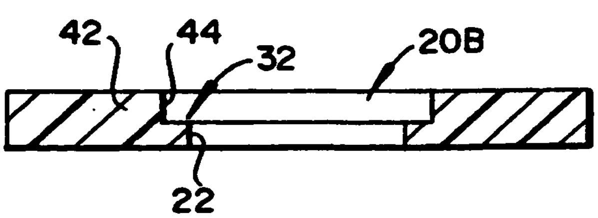


FIG. 3C

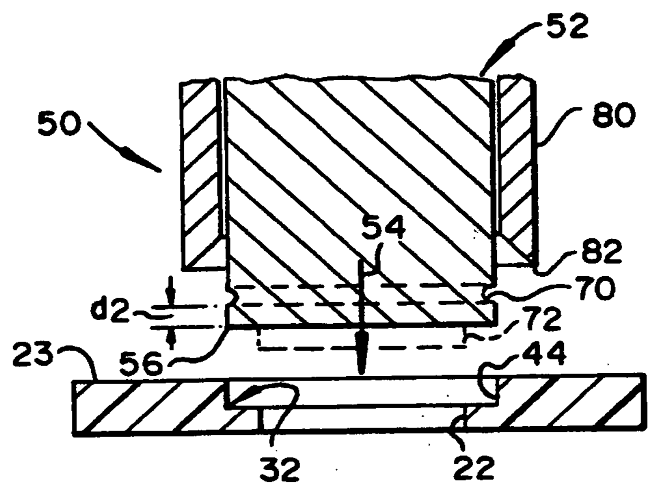


FIG. 3D

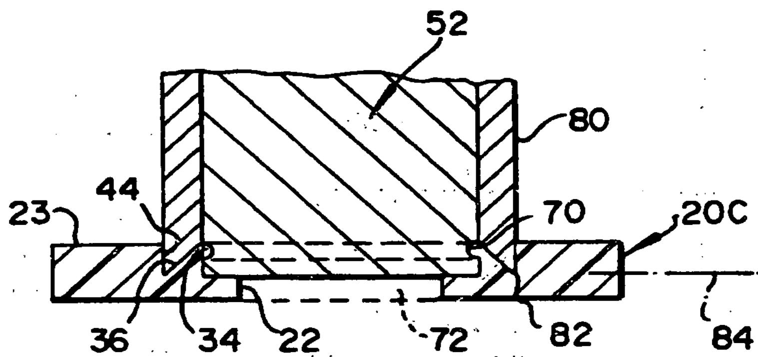


FIG. 3E

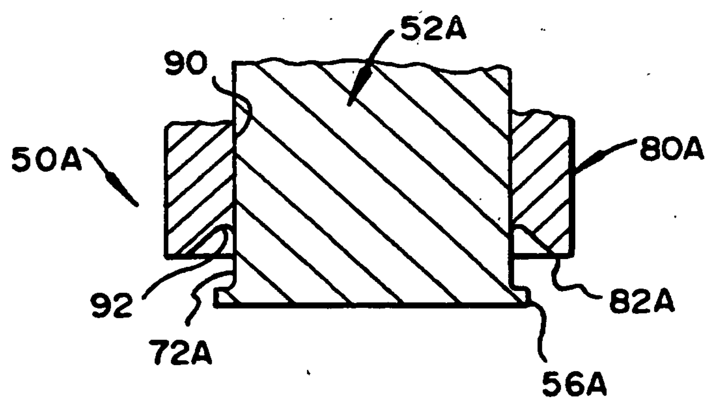


FIG. 4

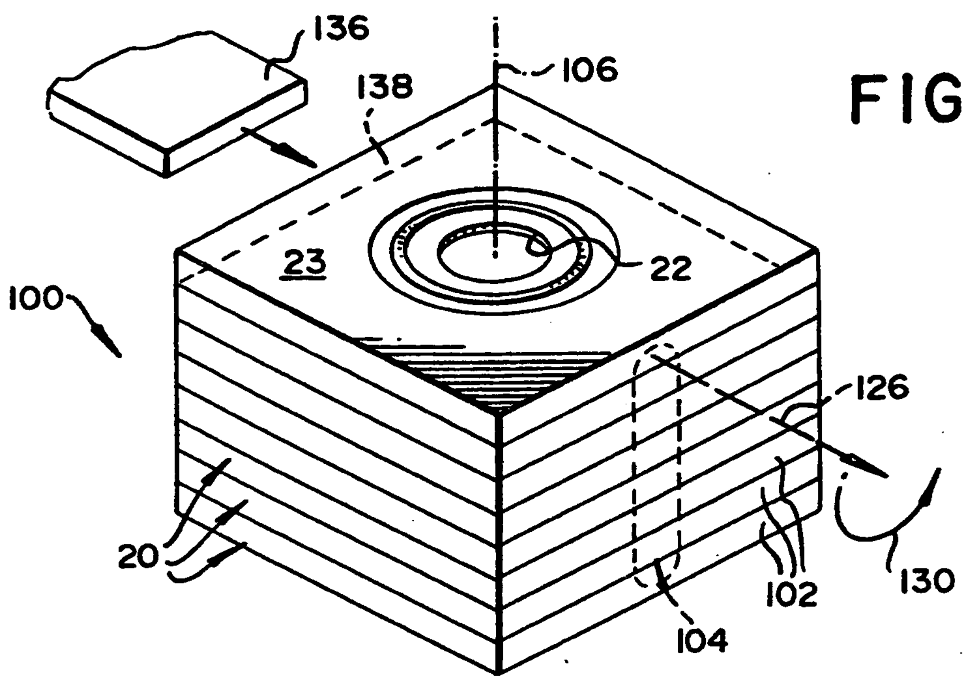


FIG. 5

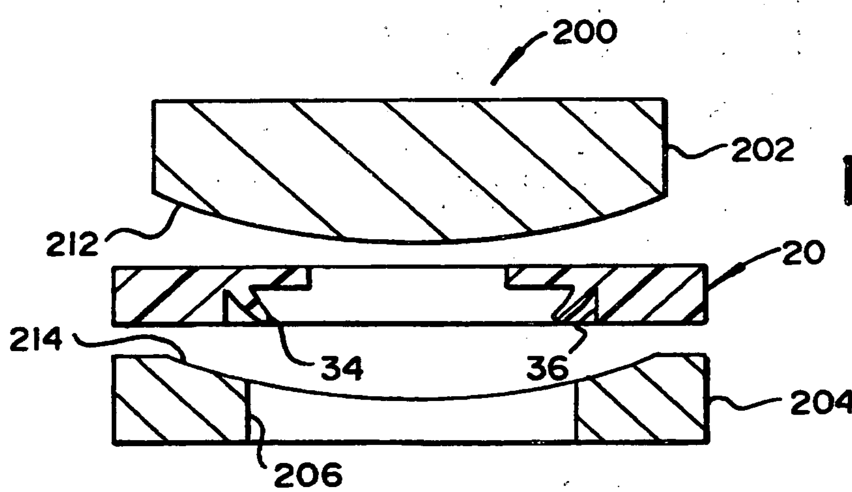


FIG.7A

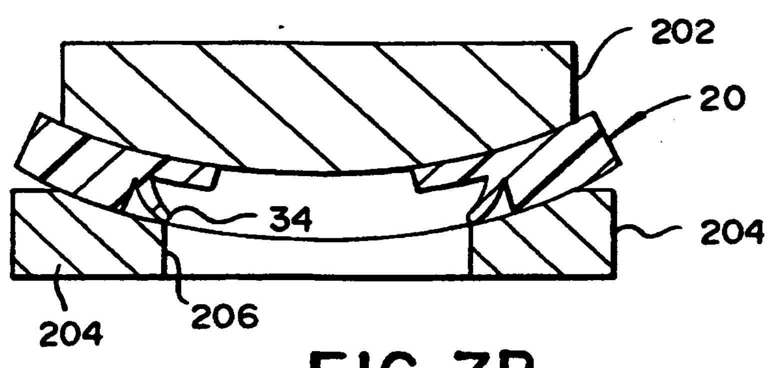


FIG. 7B

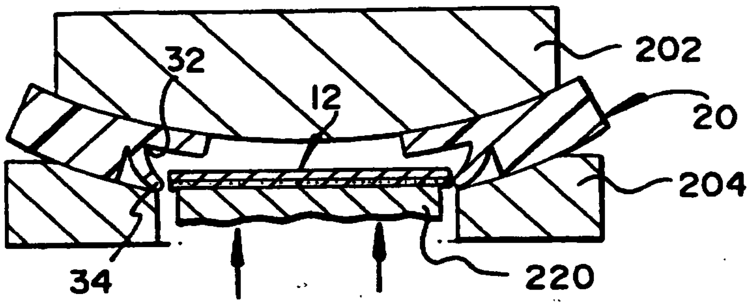


FIG. 7C

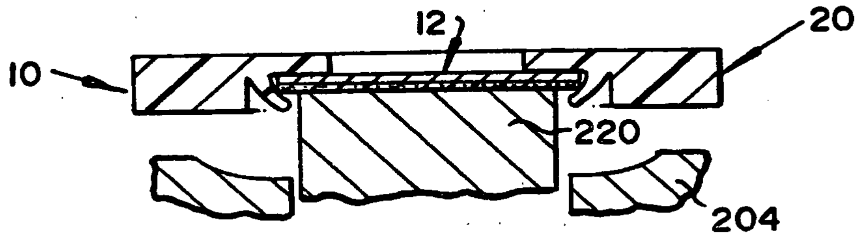


FIG. 7D

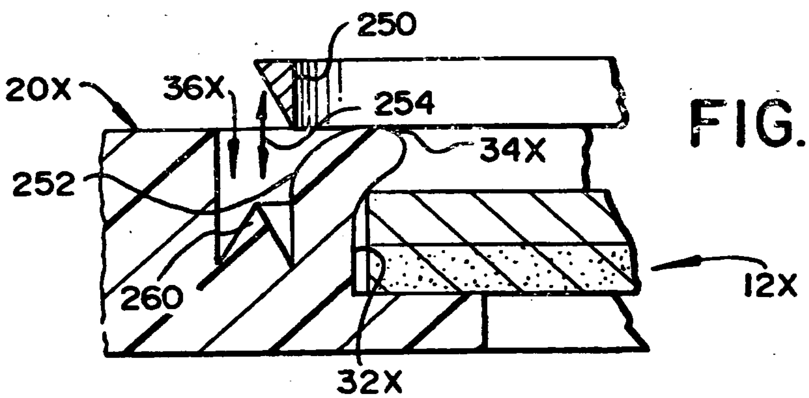


FIG.8A

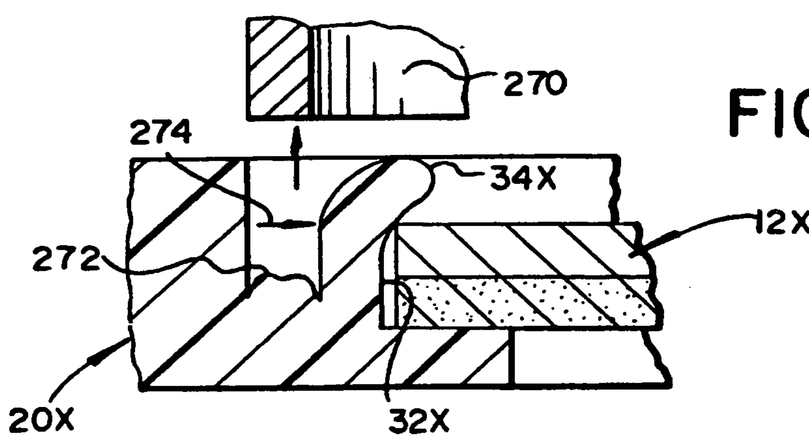


FIG. 8B

FIG. 6

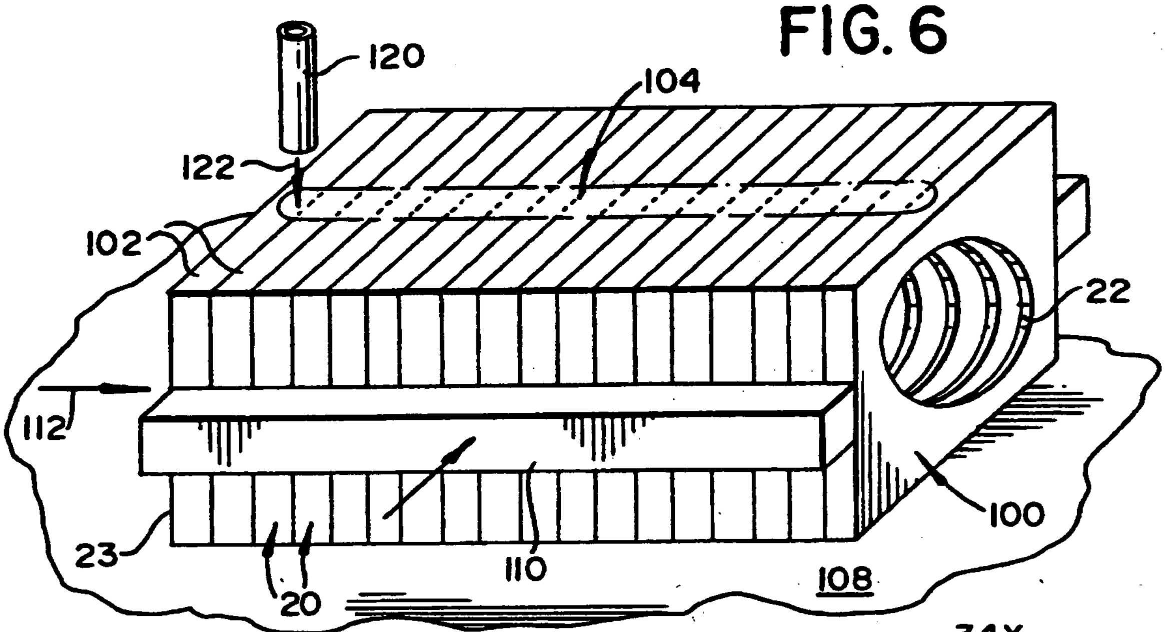


FIG. 9

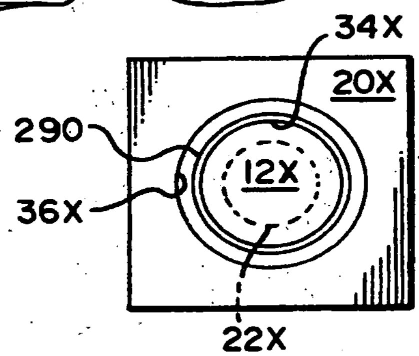


FIG. 10A

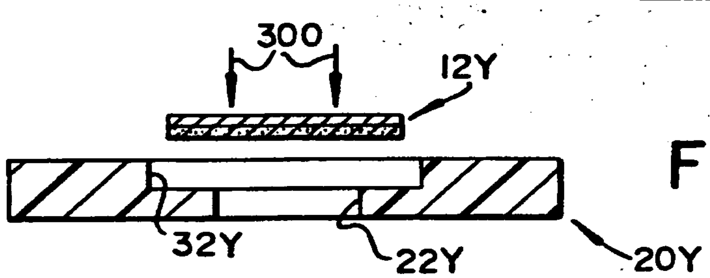
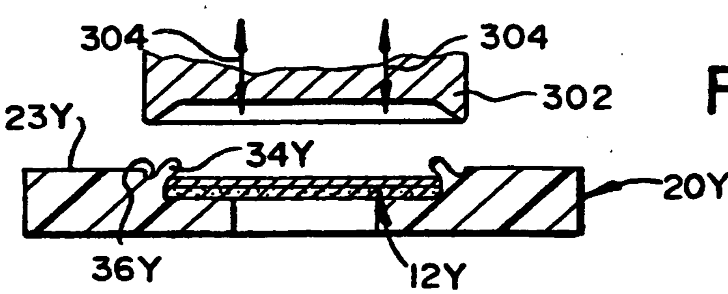


FIG. 10B



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(54) Test elements and method for manufacturing thereof.

(57) Test elements for use in clinical analyzers are usually assembled from a number of components which have fairly complex shapes and then bonded tog ther using ultrasonic welding techniques. This requires careful assembly to provide adequate bonding. Described herein is a novel slide test element (10) and a method of its manufacture. The test elem nt (10) comprises a frame member (20) having a rec ss (32) in which is retained a reaction member (12). An overhanging lip (34) is form d in a sid wall of the recess (32) to hold th reaction member (12) in position once assembled. Assembly is achieved by bending the fram member (20) with the lip (34) facing outwardly, forcing it to part a distanc suffici nt to allow the r action member (12) to b inserted, and then relaxing the frame member (20) once th r action member (12) has been inserted.

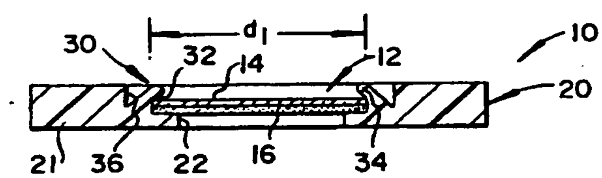

FIG. 1

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EUROPEAN SEARCH REPORT

Application Number

EP 92 20 3919

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X Y A	EP-A-0 212 634 (MILES LABORATORIES) * the whole document *	1-3 5 8,12,14	G01N35/00 B01L3/00 B29C65/56 B29C67/00 B29C69/00 B29C65/02
X A	EP-A-0 205 078 (MILES LABORATORIES) * page 3, line 8 - page 4, line 19 *	1-3 8,11,14	
Y A	AU-D-2 473 271 (BESPAK INDUSTRIES) * page 3, line 2 - page 4, line 4 *	5 14	
A	WO-A-8 300 391 (AMERICAN HOSPITAL SUPPLY CORP) * figures 4,5 *	1-5	
A	US-A-4 387 990 (FUJI PHOTO FILM CO) * column 4, line 6 - line 41; figures 4,5 *	1-5	
A	US-A-4 564 503 (GREISCH) * the whole document *	1,5	
A	US-A-4 811 861 (ROBERTS) * column 2, line 46 - column 4, line 41; figures 2-5 *	8,9	**TECHNICAL FIELDS SEARCHED (Int. Cl.5)** G01N B01L B29C
A	US-A-4 915 368 (TSUNEKAWA ET AL.) * abstract *	13	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	16 AUGUST 1993	BINDON C.A.

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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid,

namely claims:

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions,

namely:

see sheet -B-

☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid,

namely claims:

☐ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims,

namely claims:

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LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims 1-7 : Test element with lip overhanging reaction member, and method for its manufacture.

2. Claims 8-14 : Method of manufacturing a stack of test elements.